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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/249,131	02/12/1999	Tokiya Nakazato	5225	9600
7590	09/30/2004		EXAMINER	
Supervisor, Patent Prosecution Services Piper Marbury Rudnick & Wolfe LLP 1200 Nineteenth Street, N.W. Suite 400K Washington, DC 20036-2412			GUTIERREZ, ANTHONY	
			ART UNIT	PAPER NUMBER
			2857	
DATE MAILED: 09/30/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/249,131	NAKAZATO, TOKIYA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anthony Gutierrez	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 12 February 1999.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-9 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-9 is/are rejected.  
 7) Claim(s) 9 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 12 February 1999 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 9 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must not depend from another multiple dependent claim.

Claim 9 depends on any one of claims 1-8 (which therefore includes claims 4 or 5), but claims 4 and 5 are also multiple dependent, as they each depend on any one of claims 1-3. See MPEP § 608.01(n). Accordingly, claim 9 has not been further treated on the merits.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaneko (US Patent 4,920,498).

As to claims 1-3, Kaneko discloses an examination data processing apparatus for performing separation, analysis and examination in which a predetermined sample obtained by electrophoresis is scanned to obtain a waveform and the waveform is processed, comprising (Title and Abstract): means for integration of each waveform obtained by scanning (col. 10, lines 39-61, col. 5, lines 21-25, col. 2, lines 10-19); means for normalizing said waveform from integrated values of waveforms obtained by integration and an absolute amount of the sample (col. 6, line 40-col. 8, line 33, and col. 1, lines 10-40); means for storing a plurality of normalized waveforms; and means for simultaneously outputting a plurality of stored waveforms (col. 7, lines 16-53, and col. 7, lines 29-41).

As to claim 4, Kaneko discloses a time series of an analyte (col. 4, lines 18-21).

As to claim 5, Kaneko discloses different examination items for a single analyte (col. 4, lines 14-17, and 21-30).

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko (US Patent 4,920,498), in view of the Applicant's admitted prior art.

Kaneko discloses an examination data processing apparatus for performing separation, analysis and examination in which a predetermined sample obtained by electrophoresis is scanned to obtain a waveform as addressed above.

Although Kaneko discloses application of the invention to proteins contained in serum (in the above cited passages, and col. 1, lines 11-21), he does not specifically disclose applying the invention to cholesterol and triglyceride, in order to determine the phenotype of a lipid.

The Applicant, however, has admitted in the Background of the Invention, with respect to phenotypic classification of hyperlipemia, that a core part of the basic structure of the lipoprotein is formed by a triglyceride and cholesterol ester, and further that electrophoretic lipoprotein separation is employed in routine examination.

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to extend the method of Kaneko to triglyceride and cholesterol examination, in order to determine the phenotype of a lipid (with respect to hyperlipemia), since it would further the application of the method, and provide a means for diagnosing a potentially harmful health condition.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

United States Patent 3,784,789 discloses a fraction computer for a multi-component trace in which a densiometer output of the shift register is integrated over time periods.

United States Patents 3,814,255, and 3,894,844 teach the relationship between triglycerides, cholesterol, and a lipid phenotype.

United States Patent 4,118,781 discloses a valley sensor for an electrophoretic analyzer.

United States Patent 4,420,384 discloses a method for determining boundary points on an electrophoretic pattern.

United States Patent 4,592,089 discloses an electrophoretic analytical image system that includes area and intensity information.

United States Patent 5,580,747 discloses a method for a non-radioactive enzyme assay.

United States Patent 5,675,760 discloses a method for normalizing clinical test data related to a blood sample.

United States Patent 5,846,717 discloses a method for detection of nucleic acid sequences.

United States Patent 5,865,975 discloses the use of electrophoretic means in an automatic protein and/or DNA analysis system.

United States Patent 5,904,822 discloses a method for automatic analysis of electrophoretic gels.

United States Patent 5,922,184 teaches a method of computer-directed detection of paraproteins.

United States Patent Application Publication, with a provisional date of Oct. 22, 1997, teaches a method for determining analytes in various matrices, including biological fluids.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Gutierrez whose telephone number is (571) 272-2215. The examiner can normally be reached on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc Hoff can be reached on (571) 272-2216. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

-Anthony Gutierrez

9/24/04

